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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,685	06/16/2000	Kieran P. J. Mirphy	1960.196	2321

9896 7590 08/08/2003
COOK GROUP PATENT OFFICE
P.O. BOX 2269
BLOOMINGTON, IN 47402

EXAMINER

ROBERT, EDUARDO C

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 08/08/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)
	09/594,685	MIRPHY, KIERAN P. J.
	Examiner	Art Unit
	Eduardo C. Robert	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 4/30/03 & 6/9/03.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12 June 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 9, 2003 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lazarus, et al.

Lazarus, et al. disclose a kit 10 comprising a first tray 10a of components and a second tray 10b of components. The first and second tray are individually assembled and packaged and are kept sterile until use.

Claims 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Partika, et al.

Partika, et al. disclose a kit comprising a first and second tray of components (see Figure 2) which are individually assembled and packaged and kept sterile until use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Folkman in view of Shanley, et al.; Macleod, et al.; Smith, et al.; Arlers; Racz; Jiang, et al.; Singer; Draenert; Haynie; Hertzman, et al.; and Baker.

Folkman discloses a tray for medical equipment. Folkman discloses the claimed invention except for the tray having local anesthesia, local anesthesia aspiration syringe, local anesthesia aspiration needle, injection needle, liquid monomer, monomer aspiration needle, monomer aspiration syringe, mixing bowl, mixing spatula, polymer powder, opacifier, scalpel, and needle. Shanley, et al. disclose that kits or tray can include a local anesthesia injection needle. Macleod, et al. disclose that kits or tray can include a local anesthesia compound. Smith, et al. disclose a aspiration syringe for fluids (see col. 9, lines 9-11). Arlers discloses another aspiration syringe. Racz discloses an aspiration needle for fluids. Jiang, et al. disclose that liquid monomers can be on a kit or tray. Singer discloses another aspiration needle. Draenert discloses a mixing bowl and polymeric powder. Haynie discloses that a tray or kit can have a mixing spatula. Hertzman, et al. disclose that a tray or kit can include a scalpel. Baker discloses that a tray or kit can include opacifier.

As shown above, the individual components of applicant's tray or kit are well known in the prior art and because the individual components are known in the prior art, it would have

been obvious to one ordinary skill in the art at the time the invention was made to have any of these components available at the same time, e.g. as in a "kit", such as during surgery the surgeon can select the appropriately component for the particular procedure and patient.

In other words, the individual components of applicant's kit or tray are already available as prior art, merely combining the components under the rubric of a "kit" or "tray" does not result in a novel invention, even take as a whole. It is contemplated that the surgeon or any medical practitioner can meet applicant's claimed invention by simply purchasing the Shanley, et al., Macleod, et al., Smith, et al., Arlers, Racz, Jiang, et al., Singer, Draenert, Haynie, Hertzman, et al., and Baker components, and placing these components in proximity to each other or on a medical tray, e.g. Folkman's tray, so as to fall under the rubric of a kit.

Here, the novelty of the invention must reside in its whole, i.e. the kit or tray, being greater than the sum of its parts, since the parts or components of the invention are already known in the art.

With regard to claim 13, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the combination of Folkman as modified by Shanley, et al., Macleod, et al., Smith, et al., Arlers, Racz, Jiang, et al., Singer, Draenert, Haynie, Hertzman, et al., and Baker with the polymeric powder being methylmethacrylate, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed on April 30, 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that claim 17 is now directed to "a vertebroplasty kit", it is noted that a "vertebroplasty kit" means a kit for vertebroplasty and **the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations**. Ex parte Masham, 2 USPQ2d 1647 (1987). Moreover, with regard the recitation "vertebroplasty injection", again "vertebroplasty injection" means an injection for vertebroplasty and **the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations**. Ex parte Masham, 2 USPQ2d 1647 (1987). Furthermore, with regard the preamble, it is noted that the recitation "vertebroplasty" has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. Kropa v. Robie, 88 USPQ 478 (CCPA 1951).

In response to applicant's argument, with regard the 103 rejection of claims 1-16, 20, and 21, that none of the cited references are directed to performing a vertebroplasty medical procedure, it is noted **the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations**. Ex parte Masham, 2 USPQ2d 1647 (1987). Furthermore, with regard applicant's argument about the recitation "vertebroplasty components", it is noted that this just

means components for vertebroplasty and **the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations.** Ex parte Masham, 2 USPQ2d 1647 (1987). With regard applicant's argument about "bone cement assembly", again **the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations.** Ex parte Masham, 2 USPQ2d 1647 (1987).

In response to applicant's argument that none of the cited reference are directed to performing "a vertebroplasty medical procedure", it is noted that **the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations.** Ex parte Masham, 2 USPQ2d 1647 (1987).

In response to applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin, 443 F.2d 1392; 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no motivation to form a kit as claimed, it is noted that the examiner has clearly stated a surgeon or any medical practitioner can meet applicant's claimed invention by simply purchasing the Shanley, et al., Macleod, et al., Smith, et

al., Arlers, Racz, Jiang, et al., Singer, Draenert, Haynie, Hertzman, et al., and Baker components, and placing these components in proximity to each other or on a medical tray, e.g. Folkman's tray, so as to fall under the rubric of a kit. The purpose of doing this, as stated by the examiner, would be to **have any of these components available at the same time, e.g. as in a "kit", such as during surgery the surgeon can select the appropriately component for the particular procedure and patient.** Moreover, it is noted that the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale to modify may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In response to applicant's argument that none of the cited references mention a vertebroplasty procedure or how to arrange a tray of vertebroplasty components to perform such medical procedure, it is noted that **the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations.** Ex parte Masham, 2 USPQ2d 1647 (1987). Applicant is advised that perhaps he may persue a method of using the kit in a vertebroplasty procedure.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under

37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

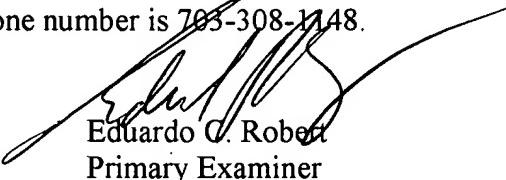
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9303 for After Final communications.

Art Unit: 3732

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C. Robert
August 5, 2003